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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,366	10/03/2005	Faramarz Jadidi	HOI-27702/16	8303

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EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	**PAPER NUMBER**
3736	

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11/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,366	JADIDI, FARAMARZ	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *85-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *85-111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/20/10; 9/29/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 99 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim discloses the use of an "associated memory" for storage of the threshold level. The current claim language does not limit the type of memory to that of a non-transitory memory, and therefore, can be reasonably interpreted to also include the use of transitory types of memory, including a signal. In order for the claimed "associated memory" to be considered to be statutory, the claimed memory must be limited to a non-transitory memory.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 85-93, 99, 102-104 and 109-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) in view of Lavigne et al (Sleep Bruxism: Validity of Clinical Research…1995).

Ober discloses a means for preventing bruxism and further discloses a sensor system operable in a setup mode for sensing muscular activity of the jaw to measure a

first level of muscular activity associated with a level of biting force; the sensor system being further operable in a use mode to measure the muscular activity of the jaw and to generate a signal corresponding thereto; a signal processor in communication with the sensor system and which is operable to receive the signals and calculate a threshold level of the muscular activity; a feedback generator in communication with the signal processor and sensor system, the feedback generator being operable to receive the third signal and generate a feedback signal is the sensor system is operating in the use mode and if the level of muscular activity exceeds the threshold level calculated by the signal processor; the feedback generator is operable to generate the feedback signal only if the measured level of activity exceeds the threshold for a predetermined period of time; the feedback generator includes a control system for controlling the intensity of the signal; the sensor system is operable to detect EMG signals; the apparatus I operable to store data derived from the sensor system and/or the signal processor and/or the feedback generator; the apparatus is operable to store the threshold in an associated memory; the signal processor is operable to determine the amplitude of the frequency content of signals from the sensor system; the signal processor is operable to carry out low pass filtering of the signals form the sensor system to filter out noise and unusable signals; and the signal processor is operable to rectify signals from the sensor system. See Column 2, lines 38-42 and 49-68; Column 3, lines 1-12 and 60-68; and Column 4, lines 1-4; in Column 3, lines 8-12, indicate the threshold can be adjusted via threshold control 32 to provide a desired predetermined level of jaw activity. This also

indicates the device is setup prior to actual use and each device would be individually setup to each person.

Ober, while disclosing the ability to setup the device, fails to explicitly disclose measuring a first level of muscle activity to generate a first signal; measuring a second level if muscle activity associated with a normally occurring jaw activity and generating a second signal; calculating a threshold that is less than 100% of the first level of muscular activity, but more than the second level of muscular activity; the signal processor is operable to calculate a threshold level in the range of 3-20% of the first level of activity; the first level of activity is associated with a maximum bite force; the second level of activity is associated with a grimace; the sensor system is operable to detect acoustic signals.

Lavigne et al disclose the ability to detect bruxism and further disclose measuring a first level of muscle activity to generate a first signal (p 548, second paragraph); measuring a second level if muscle activity associated with a normally occurring jaw activity and generating a second signal (p 548, second paragraph); calculating a threshold that is less than 100% of the first level of muscular activity, but more than the second level of muscular activity (p 548, second paragraph); the signal processor is operable to calculate a threshold level in the range of 3-20% of the first level of activity (p 548, second paragraph); the first level of activity is associated with a maximum bite force; the second level of activity is associated with a grimace (p 547, second column, second paragraph; the "rhythmic contractions" encompass a grimace); the sensor system is operable to detect acoustic signals (p 548, second paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ober to measure the signal response of a maximum bite force and a grimace as part of the setup of the device for calibrating the device for a specific user, as per the teachings of Lavigne et al, since it would provide a means of accurately setting up the device for measuring an individual's jaw movements.

4. Claims 94, 95 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) and Lavigne et al (Sleep Bruxism: Validity of Clinical Research…1995) as applied to claim 85 above, and further in view of Weinstein et al (6,270,466 B1).

Ober and Lavigne et al, as discussed above, disclose a means for detecting a bruxism event and providing feedback to the user, but fail to disclose a computer for transferring the stored data thereto; the user module is adapted to be worn on the head of the user; and a display operable to display information and/or results derived from the sensor system and/or signal processor and/or threshold generator.

Weinstein et al disclose a bruxism feedback device and further disclose a computer for transferring the stored data thereto; the user module is adapted to be worn on the head of the user; and a display (D, 102) operable to display information and/or results derived from the sensor system and/or signal processor and/or threshold generator. See Figures 2 and 5C.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ober and Lavigne et al to transfer the acquired data to a computer, wearing the system on the head and displaying

information on a display, as per the teachings of Weinstein et al, since it would provide a means of further processing the signal data, provide a unitary structure that is located on the head, and allow the user to readily ascertain how many bruxism events occurred during their sleep.

5. Claim 96 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) and Lavigne et al (Sleep Bruxism: Validity of Clinical Research…1995) as applied to claim 85 above, and further in view of Sunouchi et al (5,368,043).

Ober and Lavigne et al, as discussed above, disclose a means for preventing bruxism, but fail to disclose the apparatus comprises a slave module and a master module, the slave module being designed for wearing by a patient.

Sunouchi et al disclose a means for measuring muscle activity and further disclose the apparatus comprises a slave module and a master module, the slave module being designed for wearing by a patient (the patient unit acquires data and transmits the data to the CPU 20 for processing and display; therefore the patient unit is the slave unit and the CPU is the master unit). See Column 6, lines 65-68; and Column 9, lines 18-27.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ober and Lavigne et al to include the use of a computer within a slave/master unit setup, as per the teachings of Sunouchi et al, since it would provide an external processing means to process the data and control the feedback means.

6. Claims 98, 101, 105 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) and Lavigne et al (Sleep Bruxism: Validity of Clinical Research…1995) as applied to claim 85 above, and further in view of Massicotte et al (2004/0068196 A1).

Ober and Lavigne et al, as discussed above, disclose a means for treating bruxism using acquired EMG signals and providing feedback based on the acquired signals, but fail to disclose the apparatus is configured for frequency pattern recognition of the signals; and the frequency pattern recognition includes comparing the frequency content of the signals to the stored frequency pattern.

Massicotte et al disclose a means for trend detection in a monitoring signal and further disclose the apparatus is configured for frequency pattern recognition of the signals; and the frequency pattern recognition includes comparing the frequency content of the signals to the stored frequency pattern. See Paragraph 0057.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ober and Lavigne et al to include the use of frequency pattern recognition and comparing the frequency content of the acquired signals to the stored signals, as per the teachings of Massicotte et al, since it would provide a computer based means to recognize specific signals indicating a bruxism event, such that the user can be provided feedback to arrest the bruxism event.

7. Claim 100 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) and Lavigne et al (Sleep Bruxism: Validity of Clinical Research…1995) as applied to claim 85 above, and further in view of Prass (6,306,100 B1).

Ober and Lavigne et al, as discussed above, disclose a means for treating bruxism, but fail to teach the stored signals indicative of muscle activity are processed by FFT analysis.

Prass discloses a means for neurophysiological monitoring and further disclose the stored signals indicative of muscle activity are processed by FFT analysis. See Column 37, lines 52-59.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Weinstein et al and Ober, to include the use of FFT analysis on the stored EMG signals, as per the teachings of Prass, since it would provide a means for performing frequency analysis on the acquired EMG signals.

8. Claims 107 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477), Lavigne et al (Sleep Bruxism: Validity of Clinical Research…1995) and Massicotte et al (2004/0068196 A1) as applied to claim 101 above, and further in view of Hine et al (5,877,444).

Ober and Lavigne et al, as discussed above, disclose a means for treating bruxism using acquired EMG signals and providing feedback based on the acquired signals, but fail to disclose the frequency pattern recognition includes comparing one or more harmonic frequencies of the signals to the stored frequency pattern; and the first harmonic frequency (fundamental frequency) is compared to the stored frequency pattern.

Hine et al disclose a tuner for instruments and further disclose the frequency pattern recognition includes comparing one or more harmonic frequencies of the signals to the stored frequency pattern; and the first harmonic frequency (fundamental frequency) is compared to the stored frequency pattern. See Column 2, lines 46-53.

Even though Hine et al discloses a means for tuning instruments, Hine et al demonstrates that it is well known to acquire the first harmonic frequency of a signal and compare it to a stored frequency pattern to provide a diagnosis. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ober and Lavigne et al to include comparing the first harmonic frequency of the acquired signal to a stored frequency pattern, as per the teachings of Hine et al, since it would provide a means of accurately providing feedback to a user suffering from bruxism.

Response to Arguments

9. Applicant's arguments with respect to claims 85-111 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736